

REMARKS

Summary of the Examiner's Actions

The examiner rejected Claims 1, 8 and 13 under 35 U.S.C. § 112, indicating that there is insufficient antecedent basis for the limitation "distal end of the medical probe". Applicant acknowledges the rejection under 35 U.S.C. § 112, second paragraph.

The examiner objected to Claims 3, 4, 15 and 16 as depending from cancelled claims. Applicant acknowledges the objection.

The examiner rejected Claims 1 and 3 under 35 U.S.C. § 103(a) as being obvious under Cianci *et al.*, U.S. Patent Number 4,140,127 ("Cianci *et al.*"), in view of Wu *et al.*, U.S. Patent Number 4,246,909 ("Wu *et al.*"). Applicant acknowledges the rejection under 35 U.S.C. § 103(a).

The examiner rejected Claims 13 and 15 under 35 U.S.C. § 103(a) as being obvious under Cianci *et al.*, in view of Wu *et al.*, and in further view of Barnes *et al.*, U.S. Patent Number 3,812,769 ("Barnes *et al.*"). Applicant acknowledges the rejection under 35 U.S.C. § 103(a).

The examiner rejected Claims 4 and 16 under 35 U.S.C. § 103(a) as being obvious under Cianci *et al.*, in view of Wu *et al.*, or Barnes *et al.*, in view of Wu *et al.*, as applied to Claims 1 and 13 and further in view of Poncy, U.S. Patent Number 4,165,000 ("Poncy"). Applicant acknowledges the rejection under 35 U.S.C. § 103(a).

The examiner rejected Claims 5 and 17 under 35 U.S.C. § 103(a) as being obvious under Cianci *et al.*, in view of Wu *et al.*, and in further view of Poncy or Barnes *et al.*, in view of Poncy. Applicant acknowledges the rejection under 35 U.S.C. § 103(a).

The examiner rejected Claims 6 and 18 under 35 U.S.C. § 103(a) as being obvious under Cianci *et al.*, in view of Wu *et al.*, and in further view of Gammons *et al.*, U.S. Patent Number 6,224,543 ("Gammons *et al.*") or Barnes *et al.*, in view of Gammons *et al.*. Applicant acknowledges the rejection under 35 U.S.C. § 103(a).

The examiner rejected Claim 7 under 35 U.S.C. § 103(a) as being obvious under Cianci *et al.*, in view of Wu *et al.*, and in further view of Weaver, U.S. Patent Number 5,667,068 (“Weaver”). Applicant acknowledges the rejection under 35 U.S.C. § 103(a).

The examiner rejected Claims 8-10 under 35 U.S.C. § 103(a) as being obvious under Cianci *et al.*, in view of Poncy, and in further view of Wu *et al.* Applicant acknowledges the rejection under 35 U.S.C. § 103(a).

The examiner rejected Claim 11 under 35 U.S.C. § 103(a) as being obvious under Cianci *et al.*, in view of Poncy, and in further view of Wu *et al.*, as applied to Claim 8, and further in view of Gammons *et al.* Applicant acknowledges the rejection under 35 U.S.C. § 103(a).

The examiner rejected Claim 12 under 35 U.S.C. § 103(a) as being obvious under Cianci *et al.*, in view of Poncy, and in further view of Wu *et al.*, as applied to Claim 8, and further in view of Weaver. Applicant acknowledges the rejection under 35 U.S.C. § 103(a).

Rejections under 35 U.S.C. § 112

The examiner rejected Claims 1, 8 and 13 under 35 U.S.C. § 112, indicating that there is insufficient antecedent basis for the limitation “distal end of the medical probe”. The examiner suggested changing each instance of the language to read “distal end of a medical probe.” Applicant appreciates the examiner’s suggestion and has amended each of Claims 1, 8 and 13 accordingly.

In view of the amendment of Claims 1, 8 and 13, Applicant respectfully submits that the examiner’s rejections under 35 U.S.C. § 112 have been traversed.

Objections to the Claims

The examiner objected to Claims 3, 4, 15 and 16 as depending from cancelled claims. Specifically, the examiner noted that Claims 3 and 4 depend from cancelled Claim 2, and Claims 15 and 16 depend from cancelled Claim 14.

Accordingly, Claims 3 and 4 have each been amended to depend from Claim 1. Claims 15 and 16 have been amended to depend from Claim 13. Therefore, it is respectfully submitted that the examiners objections to the claims have been overcome.

Rejections under 35 U.S.C. § 103(a)

1. The Law of Obviousness

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

35 U.S.C. §103(a). In order to support a rejection under 35 U.S.C. § 103(a), “the examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness.” MPEP § 2142, pg. 2100-121, 8th ed. “To reach a proper determination under 35 U.S.C. § 103(a), the examiner must step backward in time and into the shoes worn by the hypothetical ‘person of ordinary skill in the art’ when the invention was unknown and just before it was made.” *Id.* The first element in establishing a *prima facie* case of obviousness is that “there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings.” MPEP § 2143, pg. 2100-122, 8th ed. The second element is that there “must be a reasonable expectation of success.” *Id.* The third element is that “the prior art reference (or references when combined) must teach or suggest all the claim limitations.” *Id.*

The relevant facts for finding obviousness relate to (1) the scope and content of the prior art, (2) the level of ordinary skill in the field of the invention, (3) the differences between the claimed invention and the prior art, and (4) any objective evidence of nonobviousness such as long felt need, commercial success, the failure of others, or copying. *Graham v. John Deere Co.*, 148 U.S.P.Q. 459, 467 (1966; *see Continental Can Co. v. Monsanto Co.*, 20 U.S.P.Q.2d 1746, 1750-51 (Fed. Cir. 1991)). The Supreme Court in *Graham* stated that "the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved." *Graham*, 383 U.S. at 17, 148 U.S.P.Q. at 467. The *Graham* court further stated that "[s]uch secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy." *Id.*

The examiner has relied on "common knowledge" in the art to support the rejection under 35 U.S.C. § 103. The standard of review applied to findings of fact is the "substantial evidence" standard under the Administrative Procedure Act (APA). *See In re Gartside*, 203 F.3d 1305, 1315, 53 U.S.P.Q.2d 1769, 1775 (Fed. Cir. 2000); *see also* MPEP 2144.03. There must be some form of evidence in the record to support an assertion of common knowledge. *See In re Lee*, 277 F.3d 1338, 1344-45, 61 U.S.P.Q.2d 1430, 1434-35 (Fed. Cir. 2002); *In re Zurko*, 258 F.3d 1379, 1386, 59 U.S.P.Q.2d 1693, 1697 (Fed. Cir. 2001); *see also* MPEP 2144.03. "With respect to core factual findings in a determination of patentability, however, the Board cannot simply reach conclusions based on its own understanding or experience—or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings." *In re Zurko*, 258 F.3d 1379, 1386, 59 U.S.P.Q.2d 1693, 1697 (Fed. Cir. 2001).

2. *The Rejection of Claims 1 and 3 under Cianci et al., in view of Wu et al.*

a. *The Examiner's Rejection*

In the rejection of Claims 1 and 3 the examiner stated:

Cianci discloses a catheter sheath having a first panel member 48a and a second panel member 48b defining a tubular configuration, the first panel being folded over to form a double thickness, and the second panel being folded over to form a double thickness (Col. 3, lines 30-40). See Fig. 2. Cianci inherently discloses the steps of providing a first panel 28a and a second panel 28b and folding the panels and heat sealing the panels to each -other. The claim 1 limitation of folding the panels prior to securement is considered to be a product by process limitation. These claims are not limited to the manipulations of the recited steps, only the structure implied but the steps. The patentability of a product does not depend on its method of production. See MPEP 2113.

Claim 1 differs from Cianci in calling for the cover to further comprise a throat. Claim 3 differs in calling for the width of the throat to be less than one half of the circumference of the medical probe. Wu teaches a cover 10 for a medical probe having a throat 37 that has been heat sealed with a width that is less than one half of the circumference of the medical probe so that the cover cannot inadvertently slide off of the probe (Col. 3, lines 18-22, 43-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover of Cianci to have a throat of less than one half the circumference of the probe as taught by Wu so that the cover cannot inadvertently slide off of the probe.

In the response to Applicant's prior arguments, the examiner stated:

Applicant argues that Cianci does not teach that the double thickness maintains the cover on the probe. The teaching reference Wu teaches that a throat has sufficient rigidity to maintain the cover on a probe, were the probe sized in such a way as to be slightly larger than the diameter of the throat. Applicant is encouraged to further define the throat and add language as to how the throat and the double thickness function to maintain the cover on the probe. The examiner points applicant to paragraph 23 of the specification for language that would further define the invention.

b. Applicant's Response

Applicant has made substantive response in the previous office action, as indicated by the examiner. Such remarks are maintained by Applicant and are incorporated herein by reference. As indicated above, and in response to the Applicant's prior remarks, the examiner has suggested claim amendments to read over the cited prior art. Applicant is appreciative of the examiner's suggestion to further define the throat and add language as to how the throat and the double thickness function to maintain the cover on the probe.

Claims 1, 8 and 13 have each been amended to further define the configuration of the first end of the cover, and specifically the portion of the cover being tapered from the first end to the throat, that portion also defining a double thickness. Each of these claims has been further amended to include a "whereby" clause setting forth that "as a medical probe is inserted into said cover and directed into and through said throat, and as said cover second end is pulled to invert said cover up to said throat, a sterile inside surface of said cover and a distal end of the medical probe are revealed". These amendments reflect the substance of Paragraph [0023] as suggested by the examiner.

It is respectfully submitted, then, that the examiner's rejections under 35 U.S.C. § 103(a) have been traversed in view of the amendments to Claim 1 as set forth.

3. The Rejection of Claims 13 and 15 under Cianci et al., in view of Wu et al, and Barnes et al.

a. The Examiner's Rejection

In the rejection of Claims 13 and 15 the examiner stated:

Claims 13 and 15 differ from Cianci in calling for the step of providing a throat with the specified circumference. Wu teaches a cover 10 for a medical probe having a throat 37 that has been heat sealed with a width that is less than one half of the circumference of the medical probe so that the cover cannot inadvertently slide off of the probe (Col. 3, lines 18-22, 43-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover of Cianci to have a throat of less than one half the circumference of the probe as taught by Wu so that the cover cannot inadvertently slide off of the probe.

Claim 13 further differs from the teachings of Cianci in view of Wu in calling for the step of folding the first and second panels before securing the members together. Barnes teaches a method of manufacturing a two ply bag including the steps of first folding the first and second panels then sealing them together (Col. 1, line 65 - Col. 2, line 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Cianci to include folding the panels before securing them as taught by Barnes as a low cost and efficient way to make a two-ply member.

b. Applicant's Response

It is respectfully submitted that the method claims of the present application as previously presented are neither anticipated nor made obvious by the cited prior art. Notwithstanding, as discussed above, Claim 13 has been amended as suggested by the examiner. For reasons provided above, therefore, it is respectfully submitted that the rejections under 35 U.S.C. § 103(a) have been traversed.

4. The Rejection of Claims 4 and 16 under Cianci et al., in view of Wu et al. or Cianci et al., in view of Barnes et al., in view of Wu et al. and Poncy

a. The Examiner's Rejection

In the rejection of Claims 4 and 16 the examiner stated:

Claim 4 differs from Cianci in view of Wu in calling for the first end of the cover to define a funnel configuration. Claim 16 differs in calling for the step of defining the funnel. Poncy teaches a medical probe cover having a first end with a flaring or funnel configuration defined by a heat sealing die to facilitate the insertion of the medical probe (Col. 4, lines 18-22). See Fig. 5. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover above to have a first end with a funnel configuration as taught by Poncy to facilitate insertion of the probe.

b. Applicant's Response

It is respectfully submitted that the claims of the present application as previously presented are neither anticipated nor made obvious by the cited prior art. Notwithstanding, as discussed above, Claims 1 and 13 have been amended as

suggested by the examiner. For reasons provided above, therefore, it is respectfully submitted that the rejections under 35 U.S.C. § 103(a) have been traversed.

5. *The Rejection of Claims 5 and 17 under Cianci et al., in view of Wu et al., and Poncy or et al., in view of Wu et al., in view of Barnes et al., in view of Poncy*

a. *The Examiner's Rejection*

In the rejection of Claims 5 and 17 the examiner stated:

Claim 5 differs from Cianci in calling for the first panel member to extend beyond the second panel. Claim 17 differs in calling for the step of defining the extended portion. Poncy teaches a cover [having] a first panel 24 that projects beyond the end of the second panel 22 to serve as a guide to facilitate inserting the probe into the sheath (Col. 3, lines 60-63). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover of Cianci to have a first panel extending beyond the second panel as taught by Poncy to facilitate insertion of the probe into the sheath.

b. *Applicant's Response*

It is respectfully submitted that the claims of the present application as previously presented are neither anticipated nor made obvious by the cited prior art. Notwithstanding, as discussed above, Claims 1 and 13 have been amended as suggested by the examiner. For reasons provided above, therefore, it is respectfully submitted that the rejections under 35 U.S.C. § 103(a) have been traversed.

6. *The Rejection of Claims 6 and 18 under Cianci et al., in view of Wu et al., and Gammons et al., or Cianci et al., in view of Wu et al., in view of Barnes et al., in view of Gammons et al.*

a. *The Examiner's Rejection*

In the rejection of Claims 6 and 18 the examiner stated:

Claim 6 differs from Cianci in calling for the cover to be partially inverted. Claim 18 differs from Cianci in view of Barnes in calling for the step of inverting the second end. Gammons teaches a sheath having a second end that has been inverted to facilitate movement of the sheath onto the tip of a medical probe (Col. 1, lines 9-11). Therefore, it would have been obvious to one of ordinary skill in the art at the time

of invention to modify the cover of Cianci to be partially inverted as taught by Gammons to facilitate movement of the sheath onto the tip of a medical probe.

b. Applicant's Response

It is respectfully submitted that the claims of the present application as previously presented are neither anticipated nor made obvious by the cited prior art. Notwithstanding, as discussed above, Claims 1 and 13 have been amended as suggested by the examiner. For reasons provided above, therefore, it is respectfully submitted that the rejections under 35 U.S.C. § 103(a) have been traversed.

7. The Rejection of Claim 7 under Cianci et al., in view of Wu et al. and Weaver

a. The Examiner's Rejection

In the rejection of Claim 7 the examiner stated:

Claim 4 differs from Cianci in calling for the cover to be fabricated of a material having elastomeric properties. Weaver teaches a protective cover for a medical probe formed of an elastic material so that the cover can protect the delicate probe (Col. 2, lines 61-66). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover of Cianci to be formed of an elastic material as taught by Weaver to protect the delicate probe.

b. Applicant's Response

It is respectfully submitted that the claims of the present application as previously presented are neither anticipated nor made obvious by the cited prior art. Notwithstanding, as discussed above, Claim 1 has been amended as suggested by the examiner. For reasons provided above, therefore, it is respectfully submitted that the rejections under 35 U.S.C. § 103(a) have been traversed.

8. The Rejection of Claims 8-10 under Cianci et al., in view of Poncy and Wu et al.

a. The Examiner's Rejection

In the rejection of Claims 8-10 the examiner stated:

Cianci discloses a catheter sheath having a first panel member 48a and a second panel member 48b defining a tubular configuration, the first panel being folded over to form a double thickness, and the second panel being folded over to form a double thickness (Col. 3, lines 30-40). See Fig. 2.

Claim 8 differs from Cianci in calling for the first panel member to extend beyond the second panel. Poncy teaches a cover [having] a first panel 24 that projects beyond the end of the second panel 22 to serve as a guide to facilitate inserting the probe into the sheath (Col. 3, lines 60-63). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover of Cianci to have a first panel extending beyond the second panel as taught by Poncy to facilitate insertion of the probe into the sheath.

Claim 8 further differs from Cianci in view of Poncy in calling for [] the cover to further comprise a throat. Claim 9 differs in calling for the width of the throat to be less than one half of the circumference of the medical probe. Wu teaches a cover 10 for a medical probe having a throat 37 with a width that is less than one half of the circumference of the medical probe so that the cover cannot inadvertently slide off of the probe (Col. 3, lines 18-22, 43-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover of Cianci to have a throat of less than one half the circumference of the probe as taught by Wu so that the cover cannot inadvertently slide off of the probe.

Claim 10 differs from the teachings above in calling for the cover to have a funnel configuration. Poncy teaches a medical probe cover having a first end with a flaring or funnel configuration to facilitate the insertion of the medical probe (Col. 4, lines 18-22). See Fig. 5. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover above to have a first end with a funnel configuration as taught by Poncy to facilitate insertion of the probe.

b. Applicant's Response

It is respectfully submitted that the claims of the present application as previously presented are neither anticipated nor made obvious by the cited prior art. Notwithstanding, as discussed above, Claim 8 has been amended as suggested by the

examiner. For reasons provided above, therefore, it is respectfully submitted that the rejections under 35 U.S.C. § 103(a) have been traversed.

9. *The Rejection of Claim 11 under Cianci et al., in view of Poncy, Wu et al. and Gammons et al.*

a. *The Examiner's Rejection*

In the rejection of Claim 11 the examiner stated:

Claim 11 differs from the teachings above in calling for the cover to be partially inverted. Gammons teaches a sheath having a second end that is inverted to facilitate movement of the sheath onto the tip of a medical probe (Col. 1, lines 9-11). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover above to be partially inverted as taught by Gammons to facilitate movement of the sheath onto the tip of a medical probe.

b. *Applicant's Response*

It is respectfully submitted that the claims of the present application as previously presented are neither anticipated nor made obvious by the cited prior art. Notwithstanding, as discussed above, Claim 8 has been amended as suggested by the examiner. For reasons provided above, therefore, it is respectfully submitted that the rejections under 35 U.S.C. § 103(a) have been traversed.

10. *The Rejection of Claim 12 under Cianci et al., in view of Poncy in view of Wu et al., in view of Weaver*

a. *The Examiner's Rejection*

In the rejection of Claim 12 the examiner stated:

Claim 12 differs from the teachings above in calling for the cover to be fabricated of a material having elastomeric properties. Weaver teaches a protective cover for a medical probe formed of an elastic material so that the cover can protect the delicate probe (Col. 2, lines 61-66). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover above to be formed of an elastic material as taught by Weaver to protect the delicate probe.

b. Applicant's Response

It is respectfully submitted that the claims of the present application as previously presented are neither anticipated nor made obvious by the cited prior art. Notwithstanding, as discussed above, Claim 8 has been amended as suggested by the examiner. For reasons provided above, therefore, it is respectfully submitted that the rejections under 35 U.S.C. § 103(a) have been traversed.

Summary

In view of the amendment of Claims 1, 3, 4, 8, 13, 15 and 16, and the arguments presented herein, it is believed that the above-identified patent application is in a condition for the issuance of a Notice of Allowance. Such action by the examiner is respectfully requested. If, however, the examiner is of the opinion that any of the drawings or other portions of the application are still not allowable, it will be appreciated if the examiner will telephone the undersigned to expedite the prosecution of the application.

The Commissioner is authorized to charge any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 16-1910 (27455.00).

Respectfully submitted,

PITTS & BRITTIAN, P.C.

/Jeffrey N. Cutler/

by: Jeffrey N. Cutler
Registration Number 35,486

PITTS & BRITTIAN, P.C.
P.O. Box 51295
Knoxville, Tennessee 37950-1295
(865) 584-0105 Voice
(865) 584-0104 Fax